Patient monitoring

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1 Upper airway pressure limit

1.1 First pressure limit (Paw high)

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Alarm cause:	a. The patient fights the ventilator or is coughing.
	b. The inspiration tube is kinked or obstructed.
	c. One or both pressure sensor(s) deliver(s) too high a measured value.
	d. The flow source delivers an incorrect flow.
Detection:	a. The measured value of the inspiratory pressure sensor exceeds the value of the upper airway pressure limit Paw high + Insp-Flow * Rtube_Insp.
	b. The measured value of the expiratory pressure sensor exceeds the value of the upper airway pressure limit “Paw high“.
Suppression:	a. The detection “a“ is not carried out if a failure of the inspiratory pressure sensor has been detected.
	b. The detection “b“ is not carried out if a failure of the expiratory pressure sensor has been detected.
Reaction:	a. The warning “Airway pressure high“ is generated.
	b. The current respiratory phase is interrupted if this respiratory phase prevents the lungs from exhaling through the expiratory valve.
Resetting:	a. As soon as next inspiration starts (start of inspiratory flow).
	b. Five seconds after occurrence of alarm cause.

1.2 Second pressure limit (Paw high + 5 mbar)

Alarm cause:	a. The patient fights the ventilator or is coughing. b. The inspiration tube is kinked or obstructed. c. One or both pressure sensor(s) deliver(s) too high a measured value. d. The flow source delivers an incorrect flow.
Detection:	a. The measured value of the inspiratory pressure sensor exceeds the value of the upper airway pressure limit Paw high + Insp-Flow * Rtube_Insp. for more than 200 ms. b. The measured value of the expiratory pressure sensor exceeds the value of the upper airway pressure limit “Paw high “ for more than 200 ms. c. The measured value of the inspiratory pressure sensor exceeds the value of the upper airway pressure limit Paw high + 5mbar + Insp-Flow * Rtube_Insp. for more than 48 ms. d. The measured value of the expiratory pressure sensor exceeds the value of the upper airway pressure limit “Paw high“ +5 mbar for more than 48 ms.
Suppression:	a. Detection “a“ and detection “c“ are not carried out if a failure of the inspiratory pressure sensor has been detected. b. Detection “b“ and detection “d“ are not carried out if a failure of the expiratory pressure sensor has been detected.

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Reaction:	a. The warning “Airway pressure high“ is generated. b. The current respiratory phase is interrupted and an emergency phase is initiated. c. The electrical safety valve opens. d. The message “Breathing system relieved“ is generated.
Resetting:	a. When the airway pressure reaches 5 mbar (relief successful), but at the earliest after: Adults: 500 ms; children: 150 ms. b. Five seconds after occurrence of alarm cause.

1.3 Lower airway pressure limit

Alarm cause:	a. The hose system or one of the hoses is disconnected or leaky. b. The measured value delivered by the expiratory pressure sensor is too low.

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Detection:	a. In all ventilation modes with a minimum PEEP of 3 mbar: If the airway pressure measured with the expiratory pressure sensor is below the set PEEP, the difference between the PEEP and the airway pressure will be stored in a summation memory. An alarm is given when the value in the summation memory exceeds a specific value. The summation memory is deleted if the measured airway pressure exceeds the PEEP value again. b. In volume-controlled (IPPV, SIMV, MMV), pressure-controlled (BIPAP, BIPAP (VG)) and pressure-assisted ventilation: The measured value of the expiratory pressure sensor does not reach the limit value PEE setting + threshold in two subsequent mechanical inspiration breaths for more than 100 ms in each case. The level and derivation of the threshold depend on the ventilation mode: volume controlled: 5 mbar; pressure-controlled: 0.5 * D Pinsp (Pinsp - PEEP) pressure-assisted: 0.5 * D PASB (PASB - PEEP).
Suppression:	a. Detection “a“ is activated only at PEEP settings of 3 mbar or higher. b. Detection “b“ is not activated in pure CPAP mode.
Reaction:	- The warning “Airway pressure low“ is generated.

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1.4 Minute volume

1.4.1 MV low

Alarm cause:	a. Spontaneous ventilation of the patient is insufficient. b. Spontaneous ventilation of the patient is sufficient, but the expiratory flow measured is too low due to leakages in the ventilation tube. c. The HPSV is faulty and therefore delivers too low an inspiratory flow. d. The flow sensor is faulty and therefore measured values delivered are too low.
Detection:	- The minute volume (MV) determined from the value measured by the expiratory flow sensor is below the lower minute volume limit set by the user.
Suppression:	a. After a cold start of the unit, this monitoring is suppressed automatically for 1 minute. b. After switching on the flow monitoring, the monitoring is suppressed for 2 minutes. c. Monitoring is suppressed during bronchial suction and 2 minutes afterwards. Flow monitoring is switched off.
Reaction:	The warning “MV low“ is generated.
Resetting:	The minute volume measured value exceeds the set lower minute volume limit.

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1.4.2 MV high

Alarm cause:	a. Spontaneous ventilation of the patient is too high. b. The HPSV is faulty and therefore delivers too high an inspiratory flow. c. The flow sensor is faulty and therefore measured values delivered are too high.
Detection:	a. The MV determined from the value measured by the expiratory flow sensor through filters exceeds the upper minute volume limit set by the user.
Suppression:	a. Flow monitoring is switched off.
Reaction:	a. The warning “MV high“ is generated.
Resetting:	The MV measured value is below the set upper MV limit.

1.5 FiO2

1.5.1 FiO2 low

Alarm cause:	a. The HPSV deliver an inspiratory flow with an incorrect concentration. b. The O2 sensor is faulty.
Detection:	a. The value measured by the O2 sensor is below the lower FiO2 limit.

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Suppression:	a. Calibration of the O2 sensor. b. O2 monitoring is switched off. c. Monitoring is suppressed for 1 minute after adjusting the FiO2, after calibrating the O2 sensor, and after standby.
Reaction:	a. The warning “FiO2 low“ is generated.
Other:	Bronchial suction changes the set FiO2 concentration to 100%. The limit value is also changed in the process.

1.5.2 FiO2 high

Alarm cause:	a. The HPSV deliver an inspiratory flow with an incorrect concentration. b. The O2 sensor is faulty.
Detection:	a. The value measured by the O2 sensor exceeds the upper FiO2 limit.
Suppression:	a. Calibration of the O2 sensor. b. O2 monitoring is switched off. c. Monitoring is suppressed for 1 minute after adjusting the FiO2, after calibrating the O2 sensor, and after standby.
Reaction:	a. The warning “FiO2 high“ is generated.
Other:	Bronchial suction changes the set FiO2 concentration to 100%. The limit value is also changed in the process.

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1.5.3 FiO2 limit values

The FiO2 measured value is compared with an upper and a lower limit in order to be able to generate an alarm if there is a deviation. These two limits are derived from the FiO2 setting.

Setting < 60 vol.%; lower alarm limit = setting -4 vol.%; upper alarm limit = setting +4 vol.%

Setting > = 60 vol.%; lower alarm limit = setting -6 vol.%; upper alarm limit = setting +6 vol.%

1.6 Change in breathing cycle

1.6.1 Apnea

Alarm cause:	a. Spontaneous breathing of patient has stopped. b. Hose system is disconnected or there is a major leakage. c. The flow sensor is defective.
Detection:	a. The expiration-start and expiration-end data are derived from the value measured by the flow sensor. If, in all operating modes, both data are missing for a period that is longer than the set apnea alarm time, the system will interpret this as an apnea condition. b. The inspiration start and inspiration end data are derived from the HPSV control data. If, in spontaneous and mixed operating modes, both data are missing for a period that is longer than the set apnea alarm time, the system will interpret this as an apnea condition.

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Suppression:	a. Monitoring is suppressed during calibration of an O2 sensor and during the set apnea alarm time after the calibration. b. Monitoring is suppressed during bronchial suction and during the set apnea alarm time after bronchial suction. c. An “Airway pressure high“ alarm has occurred. d. An “Airway pressure low“ alarm has occurred. e. Inspiration hold is active. f. A “Flow measurement inop“ alarm has occurred (see note). g. A “Fail to Cycle“ alarm has occurred. h. Flow monitoring is switched off (see note).
Reaction:	The warning “Apnea“ is generated.
Resetting:	At least one part of the information about inspiration (that is, start or end) and one part of the information about expiration are no longer missing.
Note:	If the “Flow measurement inop“ alarm has occurred, only that part of the monitoring is suppressed which detects the error by using the expiration start and expiration end information from the flow sensor.

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1.6.2 Fail to Cycle

Alarm cause:	a. The ventilator does no longer generate control information of the cartridge valves (HPSV). b. Due to device settings, only very low volumes can be applied if the patient's lungs are hard. c. A respiratory rate of less than 4 1/min is set in IPPV mode.
Detection:	a. The inspiration start and inspiration end data are derived from the HPSV control data. If both parts of the information are missing in pure controlled operating modes (IPPV, ILV) for longer than the set apnea alarm time, the system will interpret this as "Fail to Cycle".
Suppression:	a. Monitoring is suppressed during calibration of an O2 sensor and during the set apnea alarm time after the calibration. b. Monitoring is suppressed during bronchial suction and during the set apnea alarm time after bronchial suction. c. An "Airway pressure high" alarm has occurred. d. An "Airway pressure low" alarm has occurred. e. Inspiration hold is active. f. A different mode than IPPV is active.
Reaction:	A "Fail to Cycle" warning is generated.
Resetting:	At least one part of the inspiration start or inspiration end information is no longer missing.

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Note:	The alarms “Apnea“ and “Fail to Cycle“ are mutually exclusive because they are only mode-dependent variations.

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1.7 etCO2

1.7.1 etCO2 low

Alarm cause:	a. Hyperventilation
	b. CO2 sensor is faulty or incorrectly calibrated.
	c. Pure dead-space ventilation (Vt is too low).
Detection:	a. The measured value of the end-tidal CO2 is below the set lower limit.
Suppression:	a. Bronchial suction
	b. O2 Calibration
	c. CO2 hardware is not implemented.
	d. CO2 sensor not connected upon start-up.
	e. CO2 monitoring is switched off.
Reaction:	The warning “etCO2 low“ is generated.
Resetting:	The measured value exceeds the lower limit.

1.7.2 etCO2 high

Alarm cause:	a. Hypoventilation
	b. CO2 sensor is faulty or incorrectly calibrated.
Detection:	a. The measured value of the end-tidal CO2 exceeds the set upper limit.
Suppression:	a. Bronchial suction
	b. O2 Calibration
	c. CO2 hardware is not implemented.
	d. CO2 sensor not connected upon start-up.
	e. CO2 monitoring is switched off.
Reaction:	The warning “etCO2 high“ is generated.
Resetting:	The measured value is below the upper limit.
Other:	If the CO2 sensor is not connected until the unit is in operating mode, the monitoring will be activated automatically. An alarm is generated if the CO2 sensor is disconnected again.

1.8 Spontaneous breathing frequency

Alarm cause:	Rapid breathing (tachypnea).

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Detection:	The calculated spontaneous breathing frequency exceeds the limit set by the user for the duration of 1 minute.
Suppression:	a. Monitoring of spontaneous breathing frequency is only active in operating modes spontaneous breathing. b. Flow monitoring is switched off.
Reaction:	The warning “Frequency high“ is generated.
Resetting:	The calculated spontaneous breathing frequency is below the set limit.

1.9 Tidal volume

1.9.1 VTi high

Alarm cause:	a. A higher tidal volume is applied in pressure-controlled, pressure-limited, or pressure-assisted ventilation due to a change in the lung condition. b. The patient breathes spontaneously.
Detection:	a. The inspiratory volume exceeded the set monitoring limit “VTi high“ in more than 3 subsequent mandatory inspirations (volume-controlled, pressure-controlled). b. The inspiratory volume exceeded the set monitoring limit “VTi high“ in more than 3 subsequent spontaneous inspirations (pressure-assisted, pure spontaneous).
Suppression:	None
Reaction:	a. The warning “VTi high“ is generated. b. A volume-controlled, pressure-controlled, or pressure-assisted inspiration is aborted.

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Resetting:	a. At the end of a mandatory inspiration, the applied tidal volume is below the set monitoring limit again. b. At the end of a spontaneous inspiration, the applied tidal volume is below the set monitoring limit again.

1.9.2 Inconstant volume

Alarm cause:	Too low a tidal volume is applied in volume-controlled ventilation with activated pressure limit“Pmax“ due to a change in the lung condition.
Detection:	The applied volume at the end of a volume-controlled inspiration is lower than the set tidal volume.
Suppression:	No volume-controlled mode activated.
Reaction:	The warning “Inconstant volume“ is generated.
Resetting:	The applied tidal volume at the end of a volume-controlled inspiration corresponds to the set tidal volume again.

1.10 Inspiratory airway temperature

Alarm cause:	a. The humidifier heats up the inspiratory gas to an excessively high level. b. The measured value delivered by breathing gas temperature sensor is too high.
Detection:	The measured value from the respiratory-gas temperature sensor exceeds the 40 degrees centigrade limit for more than 1 second.
Suppression:	Only active if the unit has detected a respiratory-gas temperature sensor.

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Reaction:	The warning “Temperature high“ is generated.
Resetting:	The measured value from the respiratory-gas temperature sensor is below the limit value.

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1.11 Functional oxygen saturation

1.11.1 SpO2 low

Alarm cause:	a. Hypoventilation b. SpO2 sensor is faulty or incorrectly calibrated. c. SpO2 sensor is positioned incorrectly.
Detection:	The measured value of the functional oxygen saturation SpO2 is below the set lower limit.
Suppression:	a. SpO2 hardware is not implemented. b. SpO2 sensor not connected upon start-up. c. SpO2 monitoring is switched off.
Reaction:	The advisory message “SpO2 low“ is generated. If the alarm cause is present more than 15 seconds, a warning “SpO2 low“ will be generated instead of the advisory message.
Resetting:	The measured value exceeds the lower limit.

1.11.2 SpO2 high

Alarm cause:	a. Hypoventilation b. The SpO2 sensor is faulty or incorrectly calibrated. c. The SpO2 sensor is positioned incorrectly.
Detection:	The measured value of the functional oxygen saturation “SpO2“ exceeds the set upper limit.
Suppression:	a. The SpO2 hardware is not implemented. b. The SpO2 sensor not connected upon start-up. c. SpO2 monitoring is switched off.
Reaction:	The advisory message “SpO2“ is generated. If the alarm cause is present more than 15 seconds, a warning “SpO2 low“ will be generated instead of the advisory message.
Resetting:	The measured value is below the upper limit.
Other:	If the SpO2 sensor is not connected until the unit is in operating mode, the monitoring will be activated automatically. An alarm will be generated if the sensor is disconnected again.

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1.12 Pulse rate

1.12.1 Pulse low

Alarm cause:	a. Change in the patient's condition. b. The SpO2 sensor is faulty or incorrectly calibrated. c. The SpO2 sensor is positioned incorrectly.
Detection:	The measured value of the pulse rate is below the set lower limit.
Suppression:	a. The SpO2 hardware is not implemented. b. The SpO2 sensor not connected upon start-up. c. SpO2 monitoring is switched off.
Reaction:	The advisory message "Pulse low" is generated If the alarm cause is present more than 15 seconds, a warning "Pulse low" will be generated instead of the advisory message.
Resetting:	The measured value exceeds the lower limit.

1.12.2 Pulse high

Alarm cause:	a. Change in the patient's condition. b. The SpO2 sensor is faulty or incorrectly calibrated. c. The SpO2 sensor is positioned incorrectly.

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Detection:	The measured value of the pulse rate exceeds the set upper limit.
Suppression:	a. The SpO2 hardware is not implemented. b. The SpO2 sensor not connected upon start-up. c. SpO2 monitoring is switched off.
Reaction:	The advisory message “Pulse high“ is generated. If the alarm cause is present more than 15 seconds, a warning “Pulse high“ will be generated instead of the advisory message.
Resetting:	The measured value is below the upper limit.

1.12.3 No pulse

Alarm cause:	a. Change in the patient’s condition. b. The SpO2 sensor is faulty or incorrectly calibrated. c. The SpO2 sensor is positioned incorrectly.
Detection:	The SpO2 module could not measure a pulse for 15 seconds.
Suppression:	a. The SpO2 hardware is not implemented. b. The SpO2 sensor not connected upon start-up. c. SpO2 monitoring is switched off.
Reaction:	The warning “No pulse“ is generated.
Resetting:	The measured value is below the upper limit.

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Other:	If the SpO2 sensor is not connected until the unit is in operating mode, the monitoring will be activated automatically. An alarm will be generated if the sensor is disconnected again.

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2 Device monitoring

2.1 Airway pressure sensors

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Alarm cause:	a. One sensor is faulty. b. Offset voltage of one pressure sensor or both pressure sensors has drifted too much. c. The pressure sensors are no longer supplied with voltage. d. A pressure sensor delivers incorrect, but dynamic measured values. e. The calibration valve of a pressure sensor is faulty so that the pressure sensor is either permanently switched to ambient pressure or does not correctly switch to ambient pressure during calibration.
Detection:	a. The maximum and minimum values of a pressure sensor are measured during the course of a breathing cycle. At the end of a breathing cycle, the difference between maximum and minimum is less than 1 mbar in software version 1.04 or earlier; 0.2 mbar in software version 1.05 or later. b. The offset of one pressure sensor has drifted more than 500 mV between two calibrations (3 minutes). c. After a calibration, the offset of one pressure sensor is no longer within the permissible window of 1.74 V +- 500 mV. d. At the end of an expiration, the measured values of the two pressure sensors differ by more than 5 mbar.
Suppression:	None

Reaction:	a. The warning “Pressure measurement inop“ is generated. b. If only one pressure sensor has been detected as faulty, the measured value of the faultless pressure sensor is also used as measured value for this pressure sensor. c. The faulty pressure sensor(s) will be re-calibrated. The first calibration after fault detection is done immediately, further calibrations are repeated at 15-second intervals.
Resetting:	No fault detected any more by the above mentioned detection criteria.

2.2 Flow measurement

2.2.1 Flow measurement inop (faulty flow sensor)

Alarm cause:	a. The flow sensor is faulty. b. The expiratory valve is faulty, there was a flow at the flow sensor during calibration. c. The flow sensor is disconnected.
Detection:	a. The measured value of the inop channel and/or the measurement channel is less than 0.2 V. (Scan time: 100 ms sensor OK: Inop > 0.2 V measurement > 0.2 V; measurement wire broken: Inop > 0.2 V measurement < 0.2 V; compensation wire broken: Inop < 0.2 V measurement > 0.2 V; both wires broken: Inop < 0.2 V measurement < 0.2 V. b. The measuring bridge voltage required for calibration is outside the dynamic range of the D/A converter. c. The flow sensor measured value is greater than 100 L/min for more than 15 seconds.

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Suppression:	a. Detection “a.“ and detection “c.“ are only carried out during normal operation, not during flow sensor calibration. b. Detection “b.“ is only carried out during flow sensor calibration. c. Flow monitoring is switched off.
Reaction:	The warning “Flow measurement inop“ is generated.
Resetting:	None of the above mentioned detection criteria shows an error condition.

2.2.2 Flow sensor? (Flow sensor not positioned correctly)

Alarm cause:	The flow sensor is not inserted in the patient system (flow sensor switch open).
Detection:	The flow sensor switch is detected “open“. This detection is provided with an error counter.
Suppression:	Flow monitoring is switched off.
Reaction:	The alarm “Flow sensor?“ is generated.

2.3 Oxygen measurement

Alarm cause:	a. The oxygen sensor is faulty. b. During calibration, the cartridge valves (HPSV) deliver an incorrect O2 concentration.

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Detection:	a. The value measured by the O2 sensor is below the limit of 15 vol.%.
	b. The value measured by the O2 sensor exceeds the limit of 106 vol.%.
	c. During calibration to 100 vol.%, the O2 sensor voltage is outside tolerance limits: lower limit: = 26.5 mV (cell voltage) * 47.51 = 1.257 V; upper limit: = 118.8 mV cell voltage * 47.51 = 5.644 V.
Suppression:	a. O2 monitoring is switched off.
	b. Error detection “c“ is only carried out during sensor calibration.
	c. Error detection “a“ and error detection “b“ are suppressed during calibration.
Reaction:	The warning “O2 measurement inop“ is generated.
Resetting:	a. If the alarm was generated because of criterion “a“ or “b“, it will be reset as soon as these error conditions are no longer present.
	b. If the alarm was generated because of criterion “c“, it can only be reset by re-calibrating.
Other:	The O2 concentration display value is limited to the range of 15 to 100 vol.%.

2.4 HPSV

Alarm cause:	The cartridge valve (HPSV) or the cartridge valve control (HPSV control) is faulty.
Detection:	The HPSV Control PCB reports an error on the error line F1 caused by a logical high level.
Suppression:	None

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Reaction:	a. The warning “Mixer inop“ is generated. b. If only one cartridge valve (HPSV) reports an error, the delivery of the inspiratory flow is completely assigned to the intact HPSV. c. If both cartridge valves (HPSV) report an error, the electrical safety valve opens.
Resetting:	The error line F1 is on the logical low level.
Other:	If the cartridge valve (HPSV) that is reporting an error needs to deliver a low flow or no flow at all, the advisory message “Mixer inop“ is displayed instead of the warning. Advisory ranges: - HPSV -- AIR -- FiO2 -- 0.97 - 1.00 - HPSV O2 -- FiO2 -- 0.21 - 0.24

2.5 Expiratory valve

Alarm cause:	a. The expiratory valve is faulty. b. The PEEP valve builds up an insufficient closing pressure or no closing pressure at all.
Detection:	An expiration flow was measured in more than 3 mandatory breaths during inspiration and in each inspiration the integral of the expiration flow exceeded the value of the inspiratory tidal volume by 25%. The inspiratory tidal volume was at least 12.5 mL in each case.
Suppression:	None
Reaction:	The warning “Expiratory valve inop“ is generated.
Resetting:	The first mandatory inspiration, in which the leakage through the expiratory valve is less than 25% of the inspiratory tidal volume, resets the alarm.

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2.6 Gas supplies

2.6.1 No AIR

Alarm cause:	a. The AIR supply is not connected or has failed. b. The absolute pressure sensor is faulty.
Detection:	a. The measured value of the AIR supply absolute pressure sensor remains below the limit value of 2.2 bar absolute for more than 500 ms. b. During a complete breathing cycle, the maximum measured value of the absolute pressure sensor was less than 3.5 bar absolute.
Suppression:	Device Check
Reaction:	a. The warning “No AIR“ is generated. b. The unit’s gas supply is switched to oxygen.
Resetting:	The measured value of the absolute pressure sensor is greater than 3.5 bar.
Other:	If little or no flow is taken from the AIR supply due to the set concentration, the advisory message “No AIR“ is displayed instead of the warning. Advisory ranges: HPSV Air -- FiO2 -- 0.97 - 1.00. If the unit is in device check mode, monitoring is suppressed to enable completion of the check steps.

2.6.2 No oxygen

Alarm cause:	a. The oxygen supply is not connected or has failed. b. The absolute pressure sensor is faulty.

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Detection:	a. The measured value of the oxygen supply absolute pressure sensor remains below the limit value of 2.2 bar absolute for more than 500 ms. b. During a complete breathing cycle, the maximum measured value of the absolute pressure sensor was less than 3.5 bar absolute.
Suppression:	Device Check
Reaction:	a. The warning “No oxygen“ is generated. b. The unit’s gas supply is switched to AIR.
Resetting:	The measured value of the absolute pressure sensor is greater than 3.5 bar.
Other:	If little or no flow is taken from the oxygen supply due to the set concentration, the advisory message “No oxygen“ is displayed instead of the warning. Advisory ranges: HPSV O2 -- FiO2 -- 0.21 - 0.24. If the unit is in device check mode, monitoring is suppressed to enable completion of the check steps.

2.6.3 Pressure supply too high

Alarm cause:	a. The AIR supply pressure is too high. b. The absolute pressure sensor is faulty.
Detection:	a. During a complete breathing cycle, the maximum measured value of the absolute pressure sensor was greater than 7 bar absolute.
Suppression:	None
Reaction:	The caution message “AIR supply too high“ is generated.
Resetting:	The measured value of the absolute pressure sensor is less than 7 bar.

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Other:	If little or no flow is taken from the AIR supply due to the set concentration, the advisory message “AIR supply too high“ is displayed instead of the caution message. Advisory ranges: HPSV Air -- FiO2 -- 0.97 - 1.00

2.6.4 Oxygen supply too high

Alarm cause:	a. The oxygen supply pressure is too high. b. The absolute pressure sensor is faulty.
Detection:	a. During a complete breathing cycle, the maximum measured value of the absolute pressure sensor was greater than 7 bar absolute.
Suppression:	None
Reaction:	The caution message “Oxygen supply too high“ is generated.
Resetting:	The measured value of the absolute pressure sensor is less than 7 bar.
Other:	If little or no flow is taken from the oxygen supply due to the set concentration, the advisory message “Oxygen supply too high“ is displayed instead of the caution message. Advisory ranges: HPSV O2 -- FiO2 -- 0.21 - 0.24

2.7 CO2 measurement

2.7.1 CO2 measurement inop (faulty sensor)

Alarm cause:	a. The CO2 measuring head or the CO2 module is faulty.
Detection:	The CO2 module sends an error message to the ventilation processor through the interface.

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Suppression:	a. The CO2 module is not fitted. b. The CO2 sensor is not connected upon start-up of the device. c. CO2 monitoring is switched off.
Reaction:	The warning “CO2 measurement inop“ is generated.
Resetting:	The CO2 module no longer reports an error condition.

2.7.2 CO2 measurement inop (CO2 sensor is disconnected)

Alarm cause:	a. CO2 measuring head is electrically disconnected during operation.
Detection:	The CO2 module sends an error message to the ventilation processor through the interface.
Suppression:	a. The CO2 sensor is not connected upon start-up of the device. b. CO2 monitoring is switched off.
Reaction:	The warning “CO2 sensor?“ is generated.
Resetting:	The CO2 module no longer reports an error condition.
Other:	The presence of the CO2 sensor is checked during the start-up of the unit. If no CO2 sensor is fitted, no CO2 monitoring and no CO2 sensor monitoring takes place. CO2 monitoring and CO2 sensor monitoring are activated as soon as a CO2 sensor is fitted during operation.

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2.8 Fan (electronics)

2.8.1 Fan inop

Alarm cause:	a. The fan opening is obstructed. b. The fan is faulty.
Detection:	The measured value from the internal temperature sensor exceeds the 65 degrees centigrade limit for more than 5 seconds.
Suppression:	None
Reaction:	The advisory message “Fan inop“ is generated.
Resetting:	The value measured by the sensor is below the limit of 60 degrees centigrade.

2.8.2 Faulty fan.

Alarm cause:	a. The fan opening is obstructed. b. The fan is faulty.
Detection:	The measured value from the internal temperature sensor exceeds the 70 degrees centigrade limit for more than 5 seconds.
Suppression:	None
Reaction:	The warning “Fan inop“ is generated.
Resetting:	The value measured by the sensor is below the limit of 65 degrees centigrade.

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2.9 Connection to independent-lung ventilation

Alarm cause:	a. The unit is switched off. b. The communication cable of the 2 units for independent-lung ventilation is faulty. c. The interface is faulty.
Detection:	No information (inspiration, expiration, or ventilation frequency) is sent through the communication cable of the two units for 15 seconds.
Suppression:	Monitoring is only active in the “independent-lung ventilation“ mode.
Reaction:	b. The warning “Unit coupling inop“ is generated (unit: “Synchronous inop“). c. If the error detecting unit is the slave, it will start ventilation with the set parameters in the “IPPV“ mode.
Resetting:	The above mentioned information is received again through the communication cable for 15 seconds (cyclic).

2.10 ASB breath

Alarm cause:	a. Leakage in hose system. b. There is a leak in the expiratory valve. c. The pressure sensor is faulty.

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Detection:	No fading away of inspiratory flow is detected for more than 4 seconds after the upper-range value of the ASB ramp is reached in pressure-assisted spontaneous breathing. (Fading away: the inspiratory flow becomes less than 25% of the maximum inspiratory flow of this pressure assistance.)
Suppression:	Monitoring is only active in pressure-assisted spontaneous breathing.
Reaction:	a. Pressure assistance is stopped immediately. b. After the third interruption of pressure assistance in sequence, the warning “ASB breath longer than 4 s“ is generated.
Resetting:	With pressure assistance, the inspiratory flow fades away within 4 seconds.

2.11 PEEP

Alarm cause:	a. PEEP valve is faulty. b. The expiratory valve is faulty.
Detection:	a. In more than 10 subsequent breaths, the measured end-expiratory airway pressure differs from the set PEEP by more than -5 mbar.
Suppression:	None
Reaction:	The warning “PEEP valve inop“ is generated.
Resetting:	The measured PEEP is within the range of the set PEEP -5 mbar.

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2.12 Expiratory resistance (PEEP high)

Alarm cause:	a. The bacterial filter is clogged. b. The expiratory hose is partly kinked. c. PEEP valve is faulty. d. The expiratory valve is faulty.
Detection:	a. If, during expiration, the measured airway pressure does not fall below the limit PEEP + threshold, a time counter will be decremented. An error is reported as soon as the time counter reaches the value “0“. b. In more than 10 subsequent breaths, the measured end-expiratory airway pressure differs from the set PEEP by more than +5 mbar, and there was no expiratory flow at the time of PEEP measurement.
Suppression:	None
Reaction:	a. The warning “PEEP high“ is generated. b. The electrical safety valve opens.
Resetting:	b. The time counter is reset as soon as the measured airway pressure falls below the limit PEEP + threshold. b. The measured PEEP is within the range of the set PEEP +5 mbar.

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Note:	The threshold is dependent on the set application range (adults/children). Adults: threshold = 8 mbar Children: threshold = 4.5 mbar

2.13 Respiratory-gas temperature sensor

2.13.1 Temperature measurement inop (respiratory-gas temperature sensor is faulty)

Alarm cause:	The measured value of the respiratory-gas temperature sensor is that low that a short-circuit in the respiratory-gas temperature sensor or in the respiratory-gas temperature sensor cable is likely.
Detection:	The measure value of the respiratory-gas temperature sensor falls below the limit 1% of the A/D converter reference voltage for more than 1 second.
Suppression:	Detection is only active if the unit has detected a respiratory-gas temperature sensor.
Reaction:	a. The warning “Temperature measurement inop“ is generated. b. Dashes are displayed instead of the measured value (inop).
Resetting:	The measured value of the respiratory-gas temperature sensor exceeds the limit value.

2.13.2 Temperature measurement inop (respiratory-gas temperature sensor is disconnected)

Alarm cause:	The measured value of the respiratory-gas temperature sensor is that high that a sensor cable rupture or a disconnected respiratory-gas temperature sensor is likely.

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Detection:	The measure value of the respiratory-gas temperature sensor exceeds the limit 95% of the A/D converter reference voltage for more than 1 second.
Suppression:	Detection is only active if the unit has detected a respiratory-gas temperature sensor.
Reaction:	a. The warning “Temperature sensor ?“ is generated. b. Dashes are displayed instead of the measured value (inop). c. An info text in the help line informs the user about the most likely error cause, namely a disconnection of the respiratory-gas temperature sensor.
Resetting:	The measured value from the respiratory-gas temperature sensor is below the limit value.
Other:	After power-on, the unit assumes that the respiratory-gas temperature sensor is not connected. If, during the power-on procedure (self-test) or during normal operation, the unit detects that the value falls below the above mentioned limit, both the inspiratory gas temperature monitoring and the respiratory-gas temperature sensor monitoring are activated.

2.14 Fan (pneumatics)

Alarm cause:	a. The fan is either faulty or disconnected.

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Detection:	a. The fan control current is measured with an A/D converter with measurement resistor. In normal operating mode, this control current must show fluctuations of > 50 mV. Minimum and maximum of the fan voltage are measured for 60 seconds in each case. A fault is present if the difference between maximum and minimum is less than 50 mV. b. The measured value of the fan voltage is 0 V (interruption). c. The measured value of the fan voltage is greater than or equal to 2.9 V (short-circuit).
Suppression:	None
Reaction:	The warning “Device failure xx.xx.xxx“ is generated.
Resetting:	a. The difference is greater than 50 mV again. b. The measured value of the fan voltage is between 0 and 3.3 V again.

2.15 Ambient pressure sensor

Alarm cause:	The absolute pressure sensor is faulty.
Detection:	The measured value of the absolute pressure sensor is outside the permissible value range. Value range: 600 to 1100 mbar.
Suppression:	None
Reaction:	The warning “Absolute pressure sensor inop“ is generated.
Resetting:	The measured value is within the permissible value range again; the error counter could be decremented.

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2.16 SpO2 measurement

2.16.1 SpO2 measurement inop (faulty sensor)

Alarm cause:	a. The SpO2 sensor is faulty or the SpO2 module is faulty.
Detection:	The SpO2 module sends an error message to the ventilation processor through the interface.
Suppression:	a. The SpO2 Module PCB is not fitted.
	b. The SpO2 sensor is not connected upon start-up of the unit.
	c. SpO2 monitoring is switched off.
Reaction:	The warning “SpO2 measurement inop“ is generated.
Resetting:	The SpO2 module no longer reports an error condition.

2.16.2 SpO2 measurement inop (faulty disconnected)

Alarm cause:	a. The SpO2 measuring head is electrically disconnected during operation.
Detection:	The SpO2 module sends an error message to the ventilation processor through the interface.
Suppression:	a. The SpO2 sensor is not connected upon start-up of the unit.
	b. SpO2 monitoring is switched off.
Reaction:	The warning “SpO2 measurement inop“ is generated.
Resetting:	The SpO2 module no longer reports an error condition.

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Other:	The presence of the SpO2 sensor is checked during the start-up of the unit. If no SpO2 sensor is fitted, no SpO2 monitoring and no SpO2 sensor monitoring takes place. SpO2 monitoring and SpO2 sensor monitoring are activated as soon as a SpO2 sensor is fitted during operation.

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3 Hardware monitoring

3.1 Watchdogs

The software checks the safety device because the watchdogs of the individual microprocessors are safety-relevant features. The check is carried out only during a cold start of the unit. The watchdog is checked for correct functioning only once during the cold-start sequence. To do so, the watchdog is not triggered during the test sequence, and the unit waits for a reset over the maximum duration. The watchdog is OK if the reset occurs within the maximum duration. Otherwise the watchdog is faulty. Due to the watchdog configuration, the reset source can be detected after the reset. An evaluation is only carried out if the reset has been triggered by the watchdog, not by any other reset source. The watchdog reset is accompanied by an audible alarm (hardware connection of the piezo to the reset line).

3.2 Data retention on the CPU 68332 PCB

3.2.1 Battery-backed RAM

The main microprocessor of the unit has a battery backup for the entire RAM range. This ensures that sensitive data (operating mode parameters, calibration data, log and trends) are retained after switching off the unit or in the event of a power failure. Data retention can be destroyed under the following conditions:

- The battery voltage for backing up data is insufficient
- A reset has interrupted writing to a memory cell
- An alpha particle has changed the content of a memory cell

Before using the data further, it must be checked whether the data retention has been destroyed. If a destruction is detected, the data should be restored, if possible. If data restoring is no longer possible with a justifiable effort, the data will be assigned with default values from the ROM. In this case, the unit will display the warning “Data loss“, which disappears automatically after 10 seconds.

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3.2.2 EEPROM

The main microprocessor of the unit is equipped with an electrically erasable programmable read-only memory (EEPROM). This memory holds all configuration data. Even if all data in the battery-backed RAM are lost, the unit still has the user settings. Apart from a fault in the component, the data retention in the EEPROM may also be destroyed by a reset during the write operation. Therefore, it must be checked whether the data retention has been destroyed before using these data. If a destruction is detected, the data should be restored, if possible. If data restoring is no longer possible, the data will be assigned with default values from the ROM. In this case, the unit will display the warning “Data loss“, which disappears automatically after 10 seconds.

3.2.3 RAM

All RAM areas of all microprocessors are subjected to a RAM test. This RAM test is carried out once after a cold start and during the self test in order to locate a possible error source.

3.2.4 ROMs

All ROM areas of all microprocessors are subjected to a ROM test. This ROM test is carried out once after a power-on sequence and during the self test in order to locate a possible error source. A ROM test is also carried out cyclically during the program sequence, at which point the cells to be tested per program cycle are adapted to the run-times.

3.3 I/Os

These components are checked during the program sequence, not immediately after switching the unit on.

3.3.1 Monitoring of the AIR-O2 changeover valve

Monitoring during the device check. The function of the AIR-O2 changeover valve is checked during the device check. If a failure is detected during this check, the warning “Changeover valve inop“ is generated. The warning can be cancelled only by repeating the device check or by switching the device off and on again. Monitoring during operation. If drugs are nebulized, an incorrect position of the AIR-O2 changeover valve can lead to a corruption of the applied oxygen concentration (FiO2).

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Therefore, during drug nebulization, the requested position of the AIR-O2 changeover valve is continually compared with the feedback signal from the control electronics. A device error message is generated if the requested position and the feedback signal do not match.

3.3.2 Monitoring of the nebulizer valve

The requested position of the nebulizer is continually compared with the feedback signal from the control electronics. A device error message is generated if the requested position and the feedback signal do not match.

3.3.3 Monitoring of the safety valve

The function of the safety valve is checked during the device check. If a malfunction is detected, the warning “Safety valve inop“ will be generated. The warning can be cancelled only by repeating the device check or by switching the device off and on again.

3.4 Timing of the power-on test

The maximum times of the power-on test have been considered in the design of the system behavior with respect to communication between the individual components.

3.5 5V monitoring

The 5V monitoring device of the CPU 68332 PCB is checked for undervoltage or overvoltage immediately after switching on the unit (cold start). An undervoltage or overvoltage is simulated using test lines. The faulty voltage must trigger a hardware reset. A device fault is generated if no reset is triggered.

3.6 Reset lines

The reset lines CPU -> pneumatics, pneumatics -> CPU, and CPU -> display are checked by activation of a hardware reset once after switching the unit on (cold start). As a result of the reset of another microprocessor, the respective microprocessor should, for example, detect an interruption of communication. A device fault is generated if no reset is triggered.

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3.7 A/D converter

The operating voltages of the pressure sensors are monitored in order to check the A/D converter. The +10 V reference voltage for the pressure sensors is generated from the +15 V operating voltage. Both are present at the inputs of the A/D converter (A/D converter is mounted on the CO2 Carrier PCB). If the voltages fall below the nominal voltages by more than 1 V, a device malfunction will be generated.

3.8 Operating voltages

The operating voltages available through an A/D converter are cyclically compared with defined tolerances of 20%. If these tolerances are exceeded for more than 5 seconds, it will lead to a malfunction message.

3.9 GoldCap voltage

In the event of a power failure, the GoldCap capacitor powers the piezo alarm sound generator, thus generating an audible power failure alarm. The duration of the alarm depends on the capacity of the GoldCap capacitor. Both the function and the capacity are checked hourly, for the first time 5 minutes after switching on the unit.

A device malfunction is reported if one of the following criteria applies:

- The charging end voltage is too high (greater than or equal to 11 V): Voltage regulator is faulty.
- The charging end voltage is too low (less than 8 V): Charging circuit is faulty.
- The reference voltage is too high (greater than or equal to 6.3 V): Discharging switch is faulty.
- The reference voltage is too low (less than 4.5 V): no GoldCap fitted.
- The voltage of the GoldCap capacitor has decreased by more than 10% of the reference voltage within 4 seconds: GoldCap capacity is insufficient.

If the GoldCap capacitor test is interrupted by a piezo alarm (e.g. LED test or safety software alarm), the test will be aborted. The test is repeated after a 10-minute charging period.

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3.10 Voltage of the rechargeable batteries

If the system detects an optional internal battery in the DC/DC module of the power pack, this battery will be compared with defined limit values. The same procedure is applied to an optional external battery. In both cases, an alarm message will be generated if the defined limit values are exceeded.

Limit values:

< 10.8 V ---> battery polarities reversed

> 30 V ---> wrong battery

If an optional DC/DC module is fitted, the unit can be powered from three voltages sources that have the following priorities:

- Mains voltage
- external battery
- Internal battery

In the event of a mains power failure, the unit will first switch over to external battery supply. If the voltage is insufficient, the DC/DC will then switch over to internal battery. A status signal tells the unit whether the internal battery is fully charged or not. The battery is no longer fully charged as soon as the unit switched to internal battery. The guaranteed operating duration of 10 minutes is monitored by a counter and reported to the user through different alarm messages.

Battery voltage monitoring:

Battery status	Counter	Alarm message
full	10 minutes	None
not full	< 10 min	Advisory message “Internal battery activated“
not full	< 2 min	Caution message “Battery only 2 min left“

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not full	0 minutes	Warning message “Battery not full“

If the unit switches back to mains power supply after activation of the internal battery, the counter will be incremented, however much slower than during the discharge process.

3.11 Inop monitoring of the loudspeaker

The control signal of the loudspeaker is picked up with a protective resistor and supplied to the system in digital format. The signal is used to carry out a target-actual comparison of the loudspeaker control. A device malfunction is reported if an error is detected.

3.12 Internal interfaces

The internal interfaces (CAN, RS232) are checked for correct functioning while they are in use. A fault condition will result in a device malfunction message.

3.13 Piezo alarm generator

The piezo alarm generator generates an alarm if the mains power or the CPU fails (standstill). To do so the piezo alarm generator is controlled by the TPU. If its cyclic clock signals are absent, the piezo alarm generator muting generated from them is cancelled and a continuous beep sounds. Muting is cancelled intentionally in order to check the piezo alarm generator. The current across the piezo alarm generator, which now increases due to the cancelled muting, can be measured as a voltage drop at a protective resistor using an A/D converter. The test is repeated at 1-hour intervals.

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4 User-controlled device check

4.1 Selection of the device check

A user-controlled device check can only be carried out in standby mode. When the unit is in standby mode, the user can see the softkey “Device check“ on the main screen page of the standby menu. When this softkey is pressed, the user can view the result of the last device check including its date on the next screen page. The checker results are sensitive data that are retained after the unit is switched off. (If the device check was carried out after the preparation of the unit, it cannot be ruled out that the unit is not switched off until it is used. But it should be possible to call up the results of the device check when the unit is used.) This screen page shows a check softkey used to start the device check.

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4.2 Total check

When the total check is selected, the complete device check is carried out including the following:

- Visual check of the patient system
- Visual check of the flow sensor
- Visual check of the (optional) thermometer
- Visual check of the hose routing
- Visual check of the (optional) CO2 sensor
- Visual check of the (optional) pediatric flow sensor
- Visual check of the humidifier
- Check of the piezo alarm generator
- Check of the AIR-O2 changeover valve
- Check of the electrical safety valve
- Calibration of the flow sensor
- Calibration of the O2 sensor
- Calibration of the (optional) CO2 sensor
- Calibration of the (optional) pediatric flow sensor
- Leak test of the hose system and measurement of the compliance

4.3 Check sequence

The device check runs automatically. The device check informs the user about the test that is currently running and prompts her/him to answer certain questions with “Yes“ or “No“. The device check can be stopped at any time by pressing the softkey “Check“. All other hardkeys are deactivated while a device check is running.

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4.4 Faults occurring during a device check

At the end of the device check, the unit displays the scope and results of the check in a check list with OK/not OK entries. The user is offered an additional softkey:

- “Repeat check“; this key can be used to repeat the selected check.

If the check was interrupted by pressing the “Check“ softkey again, the results of the uncompleted test are set to unknown.

Identification of test results:

Test OK	v
Test not OK	F
Test not performed	--

4.4.1 Repeat of the check

If the user selects a repeat of the check because the test results were not OK, only those tests will be repeated that were reported as “not OK“ or “not performed“. Only the hose system leak test is carried out again with each repeat of the check because user interactions during the other test steps require re-evaluation.

If the user selects “Check“ again from the main screen page of the standby menu, all test steps will be repeated.

4.5 Test steps of the check lists

- Visual checks
- Safety checks
- Calibrations
- Leak test

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4.5.1 Visual checks

The user is prompted to check that the patient system, the flow sensor, the AWT sensor, and the CO2 sensor are fitted and engaged correctly, and to check the filling level and the function of the humidifier. In addition, the hose system and the water traps are to be checked for completeness and correct fit.

4.5.2 Safety checks

Piezo alarm generator: The user is asked whether he/she can hear an audible signal from the piezo alarm generator.

AIR-O2 changeover valve: An automatic check of this changeover valve is only possible during the device check. During the check, the test lung is inflated up to a reference pressure. Then the supply gases must be switched off individually.

Test procedure:

1 The user is prompted to supply the unit with AIR only.
2 The AIR supply is checked with the absolute pressure sensor of the HPSV and the HPSV error line “F1“.
3 The user is prompted to connect a test lung.
4 The unit delivers a continuous flow rate of 30 L/min.
5 The test lung is filled with a reference pressure of 30 mbar (measured on the expiratory side).
6 The flow is stopped as soon as the reference pressure is reached.
7 The AIR-O2 changeover valve is switched to oxygen (O2).
8 The pressure in the lung must be reduced within a defined time window. If the pressure is not reduced, the AIR-O2 changeover valve is faulty.

If no pressure is built up in the test lung, in spite of the continuous flow, the user is prompted to supply the unit with oxygen. If a pressure is built up now, the AIR-O2 changeover valve is faulty. If there is still no pressure built-up, the electrical safety valve is faulty.

Electrical safety valve

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Electrical safety valve test procedure:

1 Connect the test lung.

2 Connect the AIR supply only.

The test lung is inflated to a pressure of 30 mbar with a continuous flow rate of 30 L/min. The pneumatic assembly generates a relief that is monitored by the pressure sensors.

3 Measure the oxygen line supply pressure.

4 Connect the oxygen supply only.

The test lung is inflated to a pressure of 30 mbar with a continuous flow rate of 30 L/min. The CPU generates a relief that is monitored by the pressure sensors.

5 Measure the AIR line supply pressure.

If the requested relief is not detected, it will lead to a device malfunction. The supply pressures of the depressurized supply lines measured during the test are the reference values for the absolute pressure sensor.

4.5.3 Calibrations

Basically, the calibrations of the sensors could be combined to a single calibration because the mechanisms of the calibrations are very similar. Both the CO2 sensor and the NeoFlow sensor are optional features that must not necessarily be available on the unit tested.

4.5.4 Leak test

Hose system:

The user is prompted to seal the Y-piece of the hose system before the test is continued. During the test, a pressure of 60 mbar is built up in the hose system by applying an inspiratory flow while the expiratory valve is closed. The flow required to maintain the pressure is measured.

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The calculation of the hose system compliance is a “by-product“ of the leak test. The hose system compliance can be calculated from the pressure built-up of 60 mbar with the necessary volume.

Airway pressure sensors:

The test of the airway pressure sensors and their valves for calibration can be carried out at the same time as the leak test. The pressure decrease wait time window of 10 seconds is used for testing. Test procedure within this time window:

1 One second wait time after reaching the filling pressure (equalization procedure).
2 The measured values from the two airway pressure sensors are compared with each other.
3 The calibration valve of the inspiratory airway pressure sensor is switched, and the measured value of the sensor is checked.
4 The calibration valve of the inspiratory sensor is switched back.
5 The calibration valve of the expiratory sensor is switched, and the measured value of the sensor is checked.
6 The calibration valve of the expiratory sensor is switched back.
7 The measured values from the two sensors are compared with each other.

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